

510(k) Summary**Date: 10/19/2006****Submitter Name and Address**

CardioNet, Inc.
1010 2nd Avenue, Suite 700
San Diego, CA 92101

NOV 14 2006

Contact Person:

Jack Gaikwad
619-243-7527

Name of Device

Trade/Proprietary Name: Model CN1004 - CardioNet ECG Monitor with Arrhythmia Detection

Common/Usual Name: Arrhythmia detector and alarm

Classification Name: CFR §870.1025 Product code DSI 'Arrhythmia Detector and Alarm'

Class: Class II, Special Controls

Predicate Device

The predicate devices selected are as follows:

1. **CardioNet Ambulatory ECG Monitor**, cleared by FDA under 510(k) number K052240; 870.1025 DSI "Arrhythmia Detector and Alarm"
2. **CardioNet Ambulatory ECG Monitor**, cleared by FDA under 510(k) number K012241; 870.1025 DSI "Arrhythmia Detector and Alarm"

Device Description

The CardioNet ECG Monitor with Arrhythmia Detection Model CN1004 is an ambulatory ECG monitor with capability to detect cardiac arrhythmias and transmit ECG data to a CardioNet staffed monitoring center.

The subject device is comprised of three (3) main components: 1) a patient-worn Sensor, 2) a Monitor (communications Gateway) and 3) a charging Base.

A Sensor acquires two (2) channels of ECG data from the patient's body. This ECG data is stored and analyzed by an automated arrhythmia analysis algorithm residing in the Sensor. When events are detected by the analysis algorithm or when indicated by the patient pressing the event key on the Monitor, the Sensor will upload the data to the Monitor. The ECG data is then uploaded to the Monitoring Center. Data can be uploaded to the Monitoring Center in a variety of ways - Transmitted via Cellular RF modem or via RF to the Base for transmission via the patient's landline telephone.

The data is received and reviewed by trained technicians using the Monitoring Services Application.

Indications for Use and Contraindications

The indications for use for the subject device are as follows:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter
8. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Contraindications:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

Technological comparison to predicate devices

The primary technological difference between the subject device and the predicate devices is that in the subject device the CardioNet proprietary QRS detector

algorithm resides in the Sensor and detection of events is performed in the Sensor instead of the Monitor. The predicate devices have algorithms residing in the Monitor. The primary reason for moving the ECG detector algorithm is to enhance performance by improving communications between Sensor and Monitor and analyzing the ECG real time.

Summary of Performance Testing

The CardioNet ECG Monitor with Arrhythmia Detection Model CN1004 meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.

- ANSI/AAMI EC 38: 1998 – Ambulatory Electrocardiographs
- ANSI/AAMI EC 57: 1998 – Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety

Substantial Equivalence Conclusion

CardioNet ECG Monitor with Arrhythmia Detection, Model CN1004 is safe, effective, and substantially equivalent to the predicate devices as supported by the descriptive information and the performance testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2006

CardioNet, Inc.
c/o Mr. Jack Gaikwad
Director RA/QA
1010 2nd Avenue, Suite 700
San Diego, CA 92101

Re: K063222

Trade Name: Ambulatory ECG Monitor with Arrhythmia Detector, Model CN 1004

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Regulatory Class: Class II

Product Code: DSI

Dated: October 19, 2006

Received: October 24, 2006

Dear Mr. Gaikwad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063222

Device Name: CardioNet Ambulatory ECG Monitor with Arrhythmia Detection

Indications for Use:

The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063222

4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter
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